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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/767,825 | 01/29/2004 | Leigh Ward | FAK-101 | 5605 |

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| EXAMINER | |
|---|---|
| FOREMAN, JONATHAN M | |
| ART UNIT | PAPER NUMBER |
| 3736 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/767,825 | WARD ET AL. | |
| | Examiner | Art Unit | |
| | JONATHAN ML FOREMAN | 3736 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *47-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-55 and 58-67* is/are rejected.

7)☒ Claim(s) *56 and 57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/29/04 and 7/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statements submitted on 1/29/04 and 7/5/07comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. They have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

### *Election/Restrictions*

2. Applicant's election with traverse of Invention I in the reply filed on 10/15/08 is acknowledged. Applicant's remarks have been found persuasive and the requirement has been withdrawn.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60 – 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regard to claim 60, limitations "monitoring means to measure bioelectrical impedance" and "analysis means to process signals" are means (or step) plus function limitations that invokes 35 U.S.C. 112, sixth paragraph. However, it is unclear whether the claim elements are means (or step) plus function limitations that invoke 35 U.S.C. 112, sixth paragraph, because they fail to include the phrase "means for". If applicant wishes to have the claim limitations treated under 35 U.S.C. 112, sixth paragraph, applicant is required to:

(a) Amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines: the phrase "means for" or "step for" must be modified by functional language and

the phrase must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or

(b) Show that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or acts for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 47, 52, 60 and 63 - 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,270 to Williams in view of JP 10000185 A to Kubota et al.

In regard to claims 47, 52, 60 and 63 – 67, Williams discloses a method and device for determining a presence or absence of tissue oedema (Col. 1, lines 43 - 47) including a current means for applying an alternating current to at least one anatomical region (Col. 2, lines 51 – 53), wherein the alternating current is a single low frequency greater than 0 kHz, but no greater than 30 kHz (Col. 2, lines 5 – 6); a monitoring means to measure bioelectrical impedance of said at least one anatomical region and produce a signal characteristic of bioimpedance for said at least one anatomical region (Col. 2, lines 55 – 56); and an analysis means to process signals from a first and a second measurement of bioelectrical impedance to obtain a result to thereby provide an indication of a presence or absence of tissue oedema (Col. 2, lines 63 – 67; Col. 7, lines 1 - 20). The first and

second measurements are of a same anatomical region separated in time. The current means includes a proximal electrode and a distal electrode in electrical communication with a power source (Col. 6, lines 44 – 51). The analysis means is at least one processing means programmed to perform analysis of data in relation to the first and second measurement of bioelectrical impedance (Col. 7, lines 1 – 20). Williams discloses means for recording bioimpedance (Col. 7, lines 1 – 20). However, Williams fails to disclose the result being compared with a value for bioelectrical impedance from a plurality of subjects unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema. Kubota et al. disclose a method and device for determining a presence or absence of tissue oedema including comparing a measured bioelectrical impedance value with a value for bioelectrical impedance from a plurality of subjects[1] unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema (See Abstract). The claims would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of comparing a measured bioelectrical impedance value with a value for bioelectrical impedance from a plurality of subjects unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema as taught by Kubota et al. with the method and device of Williams for the predictable result of judging whether or not oedema is present in the tissue.

6. Claims 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,270 to Williams in view of JP 10000185 A to Kubota et al. as applied to claim 47 above, and further in view of U.S. Patent No. 5,505,209 to Reining.

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[1] It is noted by the Examiner that "the ratio in quantity of the intra-cell liquid to the extra-cell liquid in a health person in a normal condition" would have been determined through a study with a plurality of individuals to ensure a value representative for a population.

In regard to claims 58 and 59, Williams in view of Kubota et al. fail to disclose establishing a correction factor from a plurality of subjects unaffected by tissue oedema. Reining discloses a bioelectrical impedance measuring method wherein a correction factor is established from a plurality of subjects in a normal population (See Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Williams in view of Kubota et al. to include establishing a correction factor from a plurality of subjects unaffected by tissue oedema as taught by Reining in order to minimize error in the measurement (See Abstract).

7. Claims 47 – 55 and 60 – 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,788,643 to Feldman in view of JP 10000185 A to Kubota et al.

In regard to claims 47 – 55 and 60 – 67, Feldman discloses a method and device for determining a presence or absence of tissue oedema including a current means for applying an alternating current to at least one anatomical region (Col. 2, lines 16 – 17), wherein the alternating current is a single low frequency greater than 0 kHz, but no greater than 30 kHz (Col. 5, lines 10 – 17); a monitoring means to measure bioelectrical impedance of said at least one anatomical region and produce a signal characteristic of bioimpedance for said at least one anatomical region (Col. 5, lines 33 – 36); and an analysis means to process signals from a first and a second measurement of bioelectrical impedance to obtain a result to thereby provide an indication of a presence or absence of tissue oedema (Col. 6, lines 1 – 26). The first and second measurements are of a same anatomical region separated in time (Col. 6, lines 17 – 26). The first measurement of bioelectrical impedance is of a first anatomical region of the subject and the second measurement of bioelectrical impedance is of a second anatomical region different than the first anatomical region of the same subject. The first anatomical region and the second anatomical region are paired similar anatomical regions and

wherein one of the anatomical regions is unaffected by tissue oedema. The first anatomical region and the second anatomical region are dissimilar and wherein one of the anatomical regions is unaffected by tissue oedema. The anatomical regions are limbs or parts of limbs (Col. 3, lines 57 – 60; Col. 4, line 63 – Col. 5, line 9). The single low frequency alternating current is 10kHz (Col. 5, line 14). The current means includes a proximal electrode and a distal electrode in electrical communication with a power source (Col. 4, line 63 – Col. 5, line 9). The analysis means is at least one processing means programmed to perform analysis of data in relation to the first and second measurement of bioelectrical impedance (Col. 6, lines 17 – 26). Feldman discloses means for recording bioimpedance (Col. 6, line 7). Feldman discloses comparing a bioelectrical impedance measurement to a baseline impedance value (Col. 6, lines 1 – 26), but fails to disclose the measurement being compared with a value for bioelectrical impedance from a plurality of subjects unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema. Kubota et al. disclose a method and device for determining a presence or absence of tissue oedema including comparing a measured bioelectrical impedance value with a value for bioelectrical impedance from a plurality of subjects unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema (See Abstract). The claims would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of comparing a measured bioelectrical impedance value with a value for bioelectrical impedance from a plurality of subjects[1] unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema as taught by Kubota et al. with the method and device of Feldman for the predictable result of judging whether or not oedema is present in the tissue.

***Allowable Subject Matter***

8. Claims 56 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736